

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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MARY MULLANY, :  
v. Plaintiff, : Civil Action  
v. : No. 04-11375-GAO  
WYETH, INC.; WYETH PHARMACEUTICALS, :  
INC.; WYETH-AYERST INTERNATIONAL, : **JURY TRIAL DEMANDED**  
INC.; AND INDEVUS PHARMACEUTICALS, :  
INC., F/K/A INTERNEURON  
PHARMACEUTICALS, INC., :  
Defendants. :  
----- X

**ANSWER, AFFIRMATIVE DEFENSES AND JURY  
DEMAND OF INDEVUS PHARMACEUTICALS, INC.**

Defendant, Indevus Pharmaceuticals, Inc. ("IPI"), by its attorneys, and for its Answer to the Complaint, states as follows:

### **INTRODUCTION**

1. In response to paragraph 1 of the Complaint, IPI specifically denies that Redux<sup>TM</sup> was defective or dangerous and denies that its copromotion with Wyeth-Ayerst Laboratories Division ("WALD") of Redux caused any injuries to Plaintiff. IPI admits only that it submitted research regarding the safety and efficacy of Redux to the Food and Drug Administration ("FDA") in support of a New Drug Application ("NDA"), that it marketed Redux in certain states at certain times following FDA approval of Redux and that Redux was also marketed by WALD. IPI further admits that Redux was voluntarily withdrawn from the market on or about September 15, 1997. IPI is without knowledge or information sufficient to form a belief as to the truth of the Plaintiff's allegations of injury, except IPI denies that Plaintiff's alleged injuries were caused by Redux. All other allegations of paragraph 1 are denied.

2. Paragraph 2 of the Complaint is a characterization of the Complaint and the relief sought thereby. IPI admits that Plaintiff so characterized her Complaint, but denies the characterization. IPI admits only that it submitted research regarding the safety and efficacy of Redux to the Food and Drug Administration ("FDA") in support of a New Drug Application ("NDA"), that it marketed Redux in certain states at certain times following FDA approval of Redux and that Redux was also marketed by WALD. IPI is without information sufficient to form a belief as to the truth of the allegations pertaining to the Plaintiff. IPI denies all remaining allegations.

### **JURISDICTION AND VENUE**

3. IPI denies the allegations of paragraph 3 of the Complaint.

4. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the Complaint.

5. IPI admits that its principal place of business is located in Massachusetts. To the extent that the allegations of paragraph 5 constitute conclusions of law, no response is required. IPI denies any remaining allegations of paragraph 5.

#### **GENERAL ALLEGATIONS**

6. Paragraph 6 of the Complaint is a statement of definition to which no response is required.

7. IPI denies the allegations of paragraph 7 of the Complaint.

8. IPI denies the allegations of paragraph 8 of the Complaint.

9. IPI denies the allegations of paragraph 9 of the Complaint, except that it admits only that it submitted research regarding the safety and efficacy of Redux to the Food and Drug Administration ("FDA") in support of a New Drug Application ("NDA"), that it marketed Redux in certain states at certain times following FDA approval of Redux and that Redux was also marketed by WALD.

10. IPI admits that it marketed Redux to physicians in certain states, including Massachusetts, and that American Home Products Corporation, through WALD, distributed and sold Redux in interstate commerce in accordance with its FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein at certain times following FDA approval of Redux. IPI lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10.

11. IPI denies the allegations of paragraph 11 of the Complaint.

#### **THE PARTIES**

##### **The Plaintiff**

12. IPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12, except that it denies that Plaintiff's alleged injuries were caused by dextfenfluramine.

13. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13 of the Complaint.

#### **The Defendants**

14. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14 of the Complaint.

15. In response to paragraph 15 of the Complaint, IPI admits only that Wyeth Pharmaceuticals, formerly known as WALD, marketed Redux pursuant to a Copromotion Agreement between WALD and IPI. IPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 15 of the Complaint.

16. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 16 of the Complaint.

17. In response to paragraph 17 of the Complaint, IPI admits only that its principal place of business is 99 Hayden Avenue, One Ledgemont Center, Lexington, Middlesex County, Massachusetts, and that IPI is incorporated under the laws of Delaware. IPI is without information sufficient to form a belief as to the truth of the remaining allegations of paragraph 17.

#### **FACTUAL ALLEGATIONS**

##### **Diet Drug Promotion**

18. IPI denies the allegations of paragraph 18 of the Complaint as they pertain to IPI, except that it admits only that it submitted research regarding the safety and efficacy of Redux to the Food and Drug Administration ("FDA") in support of a New Drug Application ("NDA"), that it marketed Redux in certain states at certain times following FDA approval of Redux, and that Redux was also marketed by WALD. IPI is without information sufficient to form a belief as to the truth of the remaining allegations of paragraph 18 as they may pertain to other defendants.

19. In response to the allegations of paragraph 19 of the Complaint, IPI admits that Pondimin and Redux are brand names for fenfluramine and dexfenfluramine, respectively. IPI further admits that following FDA approval, IPI marketed Redux for use in accordance with

FDA approved prescribing information and subject to the precautions, warnings and contraindications stated therein, and that Redux was also marketed by WALD. IPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the physicians. IPI denies all remaining allegations of paragraph 19.

20. IPI admits that Redux affects brain serotonin levels. IPI denies the remaining allegations of paragraph 20 of the Complaint, except that IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 20 regarding Pondimin.

21. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 21 of the Complaint.

22. IPI admits that fenfluramine and dexfenfluramine affects brain serotonin levels and that dexfenfluramine is the d-isomer of fenfluramine. IPI denies the remaining allegations of paragraph 22 of the Complaint.

23. IPI denies the allegations of paragraph 23 of the Complaint to the extent they may pertain to IPI. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23 to the extent they may pertain to other defendants.

24. IPI admits that fenfluramine prescribed in combination with phentermine has been referred to as "fen/phen." IPI denies the remaining allegations of paragraph 24 of the Complaint.

25. IPI admits that numerous prescriptions for Redux were written by physicians. IPI denies the remaining allegations of paragraph 25 of the Complaint, except that IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 25 regarding Pondimin.

26. IPI denies the allegations of paragraph 26 of the Complaint.

27. In response to paragraph 27 of the Complaint, IPI admits that it submitted research regarding the safety and efficacy of Redux to the Food and Drug Administration ("FDA") in support of a New Drug Application ("NDA").

28. To the extent the allegations of paragraph 28 of the Complaint are based on writings, IPI states that the writings speak for themselves and any attempt to characterize them is improper and is denied. IPI denies the remaining allegations of paragraph 28.

29. In response to the allegations of paragraph 29 of the Complaint, IPI states that the writings speak for themselves and any attempt to characterize them is improper and is denied. IPI denies the remaining allegations of paragraph 29 as they may pertain to IPI, and is without knowledge or information sufficient to form a belief as to the truth of the allegations as they may pertain to other defendants.

30. IPI denies the allegations of paragraph 30 as they may pertain to IPI. IPI is without knowledge or information sufficient to form a belief as to the truth of the allegations as they may pertain to other defendants.

31. In response to the allegations of paragraph 31 of the Complaint, IPI admits only that it marketed Redux in certain states at certain times following FDA approval of Redux and that Redux was also marketed by WALD. IPI denies the remaining allegations in paragraph 31 as they may pertain to IPI, and is without knowledge or information sufficient to form a belief as to the truth of the allegations as they may pertain to other defendants.

32. IPI denies the allegations of paragraph 32 of the Complaint.

33. IPI denies the allegations of paragraph 33 of the Complaint.

34. IPI denies the allegations of paragraph 34 of the Complaint.

35. IPI admits that numerous prescriptions for Redux were written by physicians. IPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning phentermine and Pondimin. IPI denies the remaining allegations of paragraph 35 of the Complaint as they may pertain to IPI, and is without knowledge or information sufficient to form a belief as to the truth of the allegations as they may pertain to other defendants.

36. In response to the allegations of paragraph 36 of the Complaint, IPI states that the writings speak for themselves and any attempt to characterize them is improper and is denied. IPI denies the remaining allegations of paragraph 36.

37. IPI denies the allegations of paragraph 37 of the Complaint, except that it admits only that IPI entered into a Patent and Know-How License Agreement with Servier as of February 7, 1990, pursuant to which Les Laboratories Servier ("Servier") granted IPI the right to manufacture, use and sell dexfenfluramine in the United States. Said Patent and Know-How License Agreement speaks for itself and any attempts by Plaintiff to characterize it are improper and are denied. IPI further admits that American Cyanamid ("Cyanamid") obtained a sublicense from IPI with respect to dexfenfluramine, that there was a "Patent and Know-How Sublicense and Supply Agreement" between Cyanamid and IPI with respect to dexfenfluramine, and that in late December 1994, American Home Products Corporation and/or its subsidiaries acquired Cyanamid. Said Agreement also speaks for itself and any attempts by Plaintiff to characterize it are improper and are denied.

38. The allegations of paragraph 38 of the Complaint constitute conclusions of law and, as such, require no response. To the extent a response is required, IPI denies the allegations of paragraph 38 of the Complaint as they may pertain to IPI, except it admits only to any duties imposed by law. IPI is without sufficient information to form a belief as to the allegations as they may pertain to other defendants.

#### **PRIMARY PULMONARY HYPERTENSION**

39. In response to paragraph 39 of the Complaint, IPI admits that an article appeared in the *New England Journal of Medicine* dated August 29, 1996, titled "Appetite-suppressant drugs and the risk of primary pulmonary hypertension" ("IPPH Study"), that Dr. Stuart Rich was one of the authors of the article and that the article reported the results of the International Primary Pulmonary Hypertension Study. The article, as well as the editions of the Physician Desk Reference cited in paragraph 39, speak for themselves and any attempts by Plaintiff to

characterize them are improper and are denied. IPI further admits that it was aware of preliminary reports of the IPPH Study, that it provided such data to the FDA and included a PPH warning based on such reports in the FDA-approved label. IPI denies the remaining allegations of paragraph 39.

40. In response to the allegations of paragraph 40 of the Complaint, IPI states that the writings speak for themselves and any attempt to characterize them is improper and are denied. IPI denies the remaining allegations of paragraph 40.

41. In response to the allegations of paragraph 41 of the Complaint, IPI states that the writings speak for themselves and any attempt to characterize them is improper and are denied. IPI denies the remaining allegations of paragraph 41.

#### **VALVULAR HEART DISEASE**

42. In response to the allegations of paragraph 42 of the Complaint, IPI states that the writings speak for themselves and any attempt to characterize them is improper and are denied. IPI denies the remaining allegations of paragraph 42.

43. IPI denies the allegations of paragraph 43 of the Complaint.

44. In response to the allegations of paragraph 44 of the Complaint, IPI states that the writings speak for themselves and any attempt to characterize them is improper and are denied. IPI denies the remaining allegations of paragraph 44 as they may pertain to IPI, and is without knowledge or information sufficient to form a belief as to the truth of the allegations as they may pertain to other defendants.

45. IPI states that the writings referenced in paragraph 45 of the Complaint speak for themselves and any attempt to characterize them is improper and are denied. IPI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 45 of the Complaint.

46. IPI denies the allegations of paragraph 46 of the Complaint.

47. IPI denies the allegations of paragraph 47 of the Complaint.

48. IPI denies the allegations of paragraph 48 of the Complaint.

49. IPI states that the writings referenced in paragraph 49 of the Complaint speak for themselves and any attempt to characterize them is improper and denied. IPI denies the remaining allegations of paragraph 49.

50. IPI states that the writings referenced in paragraph 50 of the Complaint speak for themselves and any attempt to characterize them is improper and denied. IPI denies the remaining allegations of paragraph 50 of the Complaint, except that it admits only that in August 1997, a black box warning was incorporated.

51. IPI states that the writings referenced in paragraph 51 of the Complaint speak for themselves and any attempt to characterize them is improper and denied. IPI denies the remaining allegations of paragraph 51 of the Complaint.

52. IPI admits that Pondimin and Redux were voluntarily withdrawn from the market on or about September 15, 1997. IPI states that the writings referenced in paragraph 52 of the Complaint speak for themselves and any attempt to characterize them is improper and denied. IPI denies the remaining allegations of paragraph 52 of the Complaint.

53. IPI states that the writings referenced in paragraph 53 of the Complaint speak for themselves and any attempt to characterize them is improper and denied. IPI denies the remaining allegations of paragraph 53 of the Complaint.

54. IPI admits that Pondimin and Redux have been approved by the FDA for mono-drug therapy. IPI denies the remaining allegations of paragraph 54 of the Complaint.

55. IPI denies the allegations of paragraph 55 of the Complaint.

56. IPI denies the allegations of paragraph 56 of the Complaint.

57. IPI denies the allegations of paragraph 57 of the Complaint.

58. IPI denies the allegations of paragraph 58 of the Complaint.

59. IPI denies the allegations of paragraph 59 of the Complaint.

60. IPI denies the allegations of paragraph 60 of the Complaint.

61. IPI denies the allegations of paragraph 61 of the Complaint.

62. Paragraph 62 of the Complaint contains legal conclusions to which no response is required, but to the extent that IPI must respond, IPI denies all allegations in paragraph 62.

63. IPI denies the allegations of paragraph 63 of the Complaint to the extent they may pertain to IPI. IPI is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 63 to the extent they may pertain to other defendants.

64. IPI denies the allegations of paragraph 64 of the Complaint to the extent they may pertain to IPI. IPI is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 64 to the extent they may pertain to other defendants.

65. IPI denies the allegations of paragraph 65 of the Complaint to the extent they may pertain to IPI. IPI is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 65 to the extent they may pertain to other defendants.

66. IPI denies the allegations of paragraph 66 of the Complaint to the extent they may pertain to IPI. IPI is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 66 to the extent they may pertain to other defendants.

67. IPI denies the allegations of paragraph 67 of the Complaint.

**FIRST CAUSE OF ACTION**

**(Strict Liability – Failure to Warn)**

68. In response to paragraph 68 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

69. IPI denies the allegations of paragraph 69 of the Complaint.

70. IPI denies the allegations of paragraph 70 of the Complaint.

71. IPI denies the allegations of paragraph 71 of the Complaint.

**SECOND CAUSE OF ACTION**

(Negligence)

72. In response to paragraph 72 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

73. IPI denies the allegations of paragraph 73 of the Complaint, except it admits only to any duties imposed by law. To the extent the allegations of paragraph 73 constitute conclusions of law, no response is required.

74. IPI denies the allegations of paragraph 74 of the Complaint.

75. IPI denies the allegations of paragraph 75 of the Complaint.

**THIRD CAUSE OF ACTION**

(Negligence Per Se)

76. In response to paragraph 76 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

77. IPI denies the allegations of paragraph 77 of the Complaint, except it admits only to any duties imposed by law. To the extent the allegations of paragraph 77 constitute conclusions of law, no response is required.

78. IPI denies the allegations of paragraph 78 of the Complaint.

79. IPI is without knowledge sufficient to admit or deny the allegations of paragraph 79 of the Complaint pertaining to Plaintiff's alleged injuries or behavior. To the extent that the allegations of paragraph 79 of the Complaint constitute conclusions of law, no response is required.

80. IPI denies the allegations of paragraph 80 of the Complaint.

81. IPI denies the allegations of paragraph 81 of the Complaint.

**FOURTH CAUSE OF ACTION**

**(Breach of Implied Warranty)**

82. In response to paragraph 82 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

83. Paragraph 83 of the Complaint contains legal conclusions to which no response is required. To the extent that any response is required, IPI admits only that Pondimin and Redux were marketed for use in accordance with the FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein and that IPI gave only such implied warranties, if any, imposed by law. IPI is without knowledge sufficient to form a belief as to the truth of the allegations to the extent they may pertain to other defendants.

84. In response to paragraph 84 of the Complaint, IPI is without knowledge or information sufficient to form a belief as to what Plaintiff relied upon and whether such reliance was reasonable. IPI denies the remaining allegations of paragraph 84.

85. IPI denies the allegations of paragraph 85 of the Complaint.

86. IPI denies the allegations of paragraph 86 of the Complaint.

**FIFTH CAUSE OF ACTION**

**(Breach of Express Warranty)**

87. In response to paragraph 87 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

88. Paragraph 88 of the Complaint contains legal conclusions to which no response is required. To the extent that any response is required, IPI admits only that Pondimin and Redux were marketed for use in accordance with the FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein and that IPI gave only such implied warranties, if any, imposed by law. IPI is without knowledge sufficient to form a belief

as to the truth of the allegations in paragraph 88 to the extent they may pertain to other defendants.

89. In response to paragraph 89 of the Complaint, IPI is without knowledge or information sufficient to form a belief as to what Plaintiff relied upon and whether such reliance was reasonable. IPI denies the remaining allegations of paragraph 89 to the extent they may pertain to IPI. IPI is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 89 to the extent they may pertain to other defendants.

90. IPI denies the allegations of paragraph 90 of the Complaint.

#### **SIXTH CAUSE OF ACTION**

##### **(Negligent Misrepresentation)**

91. In response to paragraph 91 of the Complaint, IPI restates its answers to the preceding paragraphs of the Complaint with the same force and legal effect as if fully set out herein.

92. IPI denies the allegations of paragraph 92 of the Complaint to the extent they may pertain to IPI. IPI is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 92 to the extent they may pertain to other defendants.

93. IPI denies the allegations of paragraph 93 of the Complaint to the extent they may pertain to IPI. IPI is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 93 to the extent they may pertain to other defendants.

94. IPI denies the allegations of paragraph 94 of the Complaint to the extent they may pertain to IPI. IPI is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 94 to the extent they may pertain to other defendants.

95. IPI denies the allegations of paragraph 95 of the Complaint to the extent they may pertain to IPI. IPI is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 95 to the extent they may pertain to other defendants.

96. IPI lacks knowledge or information sufficient to form a belief as to what Plaintiff relied upon. IPI denies the remaining allegations of paragraph 96 of the Complaint to the extent they may pertain to IPI. IPI is without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 96 to the extent they may pertain to other defendants.

97. IPI denies the allegations of paragraph 97 of the Complaint.

Plaintiff's WHEREFORE clause and prayer for relief are denied.

**GENERAL DENIAL**

IPI denies each and every allegation of the Complaint that is not specifically admitted to be true.

**AFFIRMATIVE DEFENSES**

FIRST. The Complaint and each claim contained therein fail to state a claim upon which relief can be granted.

SECOND. IPI's product in all respects met or exceeded standards of the industry at the time of its manufacture, sale, and distribution.

THIRD. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

FOURTH. IPI's product was not dangerous when used in a reasonable and foreseeable manner and for its intended purpose.

FIFTH. If Plaintiff has sustained any injuries or damages, such were the result of intervening or superseding events, factors, occurrences or conditions, which were in no way caused by IPI and for which IPI is not liable.

SIXTH. Plaintiff may not recover from IPI because the methods, standards, or techniques of designing, manufacturing, and labeling of IPI's product complied with and were in conformity with the generally recognized state of the art at the time the product was designed, manufactured, and labeled. The state-of-the-art was and is such that there was and is no generally accepted or

recognized knowledge of any defective quality of the product at issue, giving rise to no duty by IPI to warn of such allegedly defective quality.

SEVENTH. Plaintiff's claims, if any, are barred, in whole or in part, by the applicable statutes of limitations and of repose.

EIGHTH. Plaintiff's claims, if any, are barred, in whole or in part, by the doctrines of laches, waiver, unclean hands, estoppel and/or ratification.

NINTH. Plaintiff's claims pursuant to G.L. c. 93A, if any, are barred by Plaintiff's failure to give proper or timely notice.

TENTH. To the extent Plaintiff's claims relate to IPI's advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States and by applicable State Constitutions, such claims are barred.

ELEVENTH. Plaintiff's claims are barred, in whole or in part, by his/her failure to mitigate any damages allegedly sustained.

TWELFTH. Plaintiff's claims are preempted, in whole or in part, by federal laws and regulations, including (without limitation) those governing the labeling, advertisement and sale of pharmaceutical products.

THIRTEENTH. Plaintiff's claims are barred or reduced by his/her contributory and/or comparative negligence, and/or contributory and/or comparative fault.

FOURTEENTH. Plaintiff's damages, if any, were the direct result of his/her pre-existing medical conditions, and/or occurred by operation of nature or as a result of circumstances over which IPI had and continues to have no control.

FIFTEENTH. Plaintiff's injuries, if any, were not foreseeable.

SIXTEENTH. Plaintiff's claims are barred by Plaintiff's assumption of risk and consent.

SEVENTEENTH. IPI is not subject to liability under *Restatement (Second) of Torts* § 402A, comment k.

EIGHTEENTH. IPI is not subject to liability under *Restatement (Third) of Torts: Products Liability*, § 6.

NINETEENTH. Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already indemnified or will in the future, with reasonable certainty, indemnify Plaintiff in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation, or employee benefit program.

TWENTIETH. The benefits of the product at issue outweigh the risks, if any, alleged in Plaintiff's Complaint.

TWENTY-FIRST. Plaintiff's claims are barred by the intervention of a learned intermediary whose omissions, acts, or faults are the cause of Plaintiff's damages, if any.

TWENTY-SECOND. Plaintiff's claims are barred because of Plaintiff's failure to join necessary and indispensable parties.

TWENTY-THIRD. Plaintiff's claims are barred by his/her alteration, modification, abuse, and/or misuse of the product at issue.

TWENTY-FOURTH. IPI had no duty to warn the Plaintiff.

TWENTY-FIFTH. IPI's product was not unreasonably dangerous.

TWENTY-SIXTH. IPI had no actual or constructive knowledge of the dangers of the product as alleged in the Complaint.

TWENTY-SEVENTH. No action or inaction by IPI was the proximate cause of Plaintiff's injuries, if any.

TWENTY-EIGHTH. IPI's product contained no defect that was the cause of Plaintiff's injuries, if any.

TWENTY-NINTH. The warnings given by IPI were adequate.

THIRTIETH. Plaintiff has failed to allege fraud with sufficient particularity.

THIRTY-FIRST. Plaintiff's injuries, if any, were caused by his/her own failure to read or to heed the warnings given, or to follow IPI's recommendations regarding the use of the product.

THIRTY-SECOND. IPI's product was properly prepared and accompanied by proper directions and warnings.

THIRTY-THIRD. Plaintiff did not exercise reasonable care as required by the circumstances.

THIRTY-FOURTH. At the time Plaintiff used IPI's product, his/her use was unanticipated, unforeseeable, and unintended.

THIRTY-FIFTH. Adequate warnings were given to informed intermediaries.

THIRTY-SIXTH. This court is not the proper venue for Plaintiff's claims.

THIRTY-SEVENTH. IPI acted reasonably and in good faith at all times.

THIRTY-EIGHTH. Plaintiff's claims are barred by the doctrine of avoidable consequences.

THIRTY-NINTH. IPI denies any and all culpability and liability, but if IPI is ultimately found to be liable, then the liability of IPI, if any, to the Plaintiff for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities contributing to the total liability for non-economic loss, including named parties and others over whom Plaintiff could have obtained personal jurisdiction with due diligence.

FORTIETH. The Complaint fails to allege a claim for which punitive or exemplary damages can be recovered.

FORTY-FIRST. Plaintiff's claims for punitive or exemplary damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution and applicable provisions of the relevant state constitutions.

**DEFENSES RESERVED**

IPI hereby gives notice that it intends to rely upon any other defenses that may become available or apparent during the discovery proceedings in this matter and hereby reserves its right to amend its Answer and to assert any such defense.

**DEMAND FOR BIFURCATED TRIAL**

If Plaintiff is allowed to proceed to trial upon any claims for punitive or exemplary or exemplary damages, such claims, if any, must be bifurcated from the other issues.

**DEMAND FOR JURY TRIAL**

IPI demands a jury trial as to all issues so triable in this action.

WHEREFORE, Defendant IPI respectfully requests that this Court:

- (a) Grant IPI judgment on all of Plaintiff's claims and dismiss the Complaint with prejudice;
- (b) Award IPI its costs and attorneys' fees for defense of the Complaint;
- (c) Award IPI such other relief as the Court deems just and proper.

Dated: August 5, 2004  
Boston, Massachusetts

Respectfully submitted,

/s/Matthew J. Matule  
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